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Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,

Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF FOR PETITIONER MEDTRONIC, INC.

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims that would expose a manufacturer to liability for marketing a medical device design that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

RULE 29.6 STATEMENT

Petitioner Medtronic, Inc. has no parent corporation and has no nonwholly owned subsidiaries.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-36a) is reported at 56 F.3d 1335 (11th Cir. 1995). The opinion of the district court granting summary judgment against plaintiffs (Pet. App. 1b-3b) is not reported.

JURISDICTION

The court of appeals entered judgment on July 3, 1995. Medtronic filed a timely petition for rehearing on July 24, 1995, which the court of appeals denied on August 15, 1995. Medtronic filed a timely petition for certiorari on November 13, 1995, and plaintiffs filed a conditional cross-petition for certiorari on December 6, 1995. Both petitions were granted on January 19, 1996. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The appendix to Medtronic's petition for certiorari sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. 360(k), 360k; 21 C.F.R. 807.81(a)(3), 807.87, 808.1(d) (excerpt), 870.3680(b), (c). Pet. App. 1f.

STATEMENT OF THE CASE

Medical devices enhance and prolong human life. Plaintiff Lora Lohr acknowledges in her complaint that she might not be alive today without a safe and effective cardiac pacemaker system. She is just one of the many thousands of Americans who benefit from device technologies that have existed for several decades.

Medical devices often incorporate sophisticated technology. Device innovation is an inexact science, and even the safest and most effective devices will not work perfectly at all times for all users. Because of that reality, there is an inevi-

table trade-off between promoting the availability of good devices—to provide their intended benefits—and protecting the public against unsafe and ineffective devices. Over-regulation, even if based on good intentions, has the potential to endanger human health by stifling innovation in new technologies and inhibiting the manufacture and distribution of existing beneficial devices. Under-regulation has the potential to compromise health by exposing the public to unsafe and ineffective devices.

Accordingly, Congress had to strike a number of balances when it adopted the present medical device regulatory structure. This case calls on the Court to define the choice Congress made in deciding *who* should regulate device design and *how*. Did Congress, recognizing the dangers of over-regulation by the states, leave design issues to federal experts, who may authorize or proscribe the marketing of particular designs and employ a variety of remedial tools to cope with any problems discovered after marketing begins? Conversely, did Congress fear under-regulation at the federal level, leaving in place tort claims that allow juries and judges in fifty states to determine, after the fact, whether a particular design authorized for marketing by the federal experts falls beneath a state law standard of care?

The precise question presented by Medtronic's petition is whether the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts plaintiffs' state common law claims alleging defects in the design of a medical device regulated by the Food and Drug Administration ("FDA"). The medical device at issue is Medtronic's Model 4011 cardiac pacemaker lead, which is an essential component of a pacemaker system implanted in the body to help maintain the natural pace of a patient's heartbeat. The lead is designed to transmit small electrical pulses to the ventricle of the heart from another part of the implanted system—a pacemaker pulse generator—and

return signals from the heart to that generator. (R1-37-Exh. 1, at 2.)[1]

The Eleventh Circuit held that the FDCA does not pre-empt plaintiffs' state design claims, even though the FDA had reviewed and affirmatively authorized the Model 4011 for marketing pursuant to the FDCA. Because this holding exposes Medtronic to liability under state law for alleged defects in a medical device design authorized by federal law, Medtronic asks this Court to reverse the Eleventh Circuit's ruling.

A. The Federal Statutory Framework

In 1976, Congress passed the Medical Device Amendments ("MDA") to the FDCA, establishing comprehensive federal regulation of medical devices for the first time. Congress recognized that medical devices "hold the promise of improving the health and longevity of the American people" and intended that the MDA would ensure public access to safe and effective devices. See S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1976).

Because of the simultaneous need to promote safe and effective devices and to protect the public against unsafe and ineffective ones, Congress enacted the MDA as "a balanced regulatory proposal." H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). Although the statute endowed the FDA with broad new regulatory powers to guard the public from unsafe and ineffective devices, it also included provisions designed to protect innovations in device technology from being "stifled by unnecessary restrictions." *Ibid.* Congress was well

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[1] Record citations are to the volume, docket entry number, and page of the court of appeals record.

aware that this new regulatory scheme extended to potentially life-saving mechanisms: it sought to encourage research and development of "sophisticated, critically important medical devices." S. Rep. No. 33, *supra*, at 2.

1. The Express Preemption Provision

Congress had to choose whether to view state regulation as a useful supplement to its own safeguards against unsafe and ineffective devices, or as an unnecessary restriction that might impede its goal of promoting device innovation and availability. Congress expressed its choice in the following preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[2]

21 U.S.C. 360k(a). The House committee report for the MDA describes this preemption provision as a "general prohibition on non-Federal regulation," expressing a congressional intent for broad preemption of state law. H.R. Rep. No. 853, *supra*, at 45.

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[2] The applicable chapter is chapter 9 of Title 21, which encompasses the entire FDCA, 21 U.S.C. 301-395.

Congress did recognize, however, that "there are some situations in which regulation of devices by States and localities would constitute a useful supplement to Federal regulation." *Ibid.* Congress therefore included a provision authorizing states to apply for an exemption from preemption, which the FDA may grant through notice and comment rulemaking procedures. 21 U.S.C. 360k(b). The FDA may exempt a state requirement if it is more stringent than the corresponding federal requirement. The FDA also may grant an exemption if the state requirement is "required by compelling local conditions" and if compliance with the state requirement would not cause a violation of any applicable FDCA requirement. *Ibid.* To date, the FDA has granted exemptions requested by 15 states and the District of Columbia under this provision.[3]

2. FDA Authority to Ensure Safety and Effectiveness

a. Classification Requirements

In passing the MDA, Congress also granted the FDA "significant new authority . . . to assure the safety and effectiveness of medical devices," H.R. Rep. No. 853, *supra*, at 3, so that the life-enhancing benefits of device technologies sufficiently outweigh any risks. Cf. S. Rep. No. 33, *supra*, at 10. The MDA established a comprehensive regulatory structure that includes a classification scheme that

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[3] 21 C.F.R. 808.55 (California), 808.57 (Connecticut), 808.61 (Hawaii), 808.69 (Maine), 808.71 (Massachusetts), 808.77 (Nebraska), 808.80 (New Jersey), 808.81 (New Mexico), 808.82 (New York), 808.85 (Ohio), 808.87 (Oregon), 808.88 (Pennsylvania), 808.93 (Texas), 808.97 (Washington), 808.98 (West Virginia), 808.101 (District of Columbia).

distinguishes among devices based upon safety and effectiveness concerns. The FDA assigns devices to one of three classes through notice and comment rulemaking procedures. See 21 U.S.C. 360c(b)(1); 21 C.F.R. 860.84. That classification decision is based upon recommendations by a panel of experts qualified by training and experience to evaluate the safety and effectiveness of the device in question. 21 U.S.C. 360c(b)(1) and (2).

Class I devices include those the FDA believes pose no unreasonable health risks. See 21 U.S.C. 360c(a)(1)(A). Class II devices are those for which special controls may be necessary to assure safety and effectiveness. *Id.* § 360c(a)(1)(B). This case involves a device in Class III, which includes devices represented to be life-sustaining or life-supporting, or those presenting a potentially unreasonable risk of illness or injury. *Id.* § 360c(a)(1)(C).

b. Substantive Regulation and Enforcement Authority

The FDA is empowered to assure that all classes of devices on the market are reasonably safe and effective. The FDA promulgates substantive safety and effectiveness requirements ranging from labeling regulations (which establish federal standards for warnings about possible dangers and side effects of device use) to the good manufacturing practice ("GMP") regulations (which implement federal quality assurance standards for devices). 21 C.F.R. Pts. 801, 820. The requirements the FDA establishes by regulation complement other substantive safety and effectiveness requirements imposed by the statute.

Under the MDA, the FDA also has broad enforcement power to remove unsafe or ineffective devices from the market, impose sanctions for conduct that endangers public health, and prohibit that conduct in the future. The FDA uses

these enforcement powers to address conditions it detects through mandatory manufacturer reports of device malfunctions, serious injuries, and deaths, and through its comprehensive authority to inspect device establishments. See 21 U.S.C. 360i, 374. In administering the FDCA, the FDA has authority to detain devices in domestic commerce and (in concert with the Customs Service) upon import into the United States. 21 U.S.C. 334(g), 381(a). The FDA also can issue administrative cease–and–desist orders barring the distribution and use of devices that present substantial public health risks. *Id.* § 360h(e)(1)(A). In addition, the FDA can require notification of dangers a device poses to public health, *id.* § 360h(a), 360h(e)(1)(B), and can order the repair, replacement, or refund of the purchase price of a device that presents an unreasonable public health risk, *id.* § 360h(b). The FDA also can order the recall of a device, *id.* § 360h(e), or impose administrative civil penalties for violations of the statute and related regulations, see *id.* § 333(g)(1)(A). Furthermore, on behalf of the FDA, the Department of Justice enforces FDCA requirements with civil actions for seizure and injunction. See *id.* §§ 332, 334. The Department of Justice also brings criminal prosecutions under the FDCA, which provides for strict criminal liability to protect public health. See *id.* § 333; *United States* v. *Park*, 421 U.S. 658 (1975).

c. Pre-Distribution Clearance Requirements

The MDA also gave the FDA authority to prevent distribution of devices without the agency's prior review and clearance. Although the FDA does not do its own research and development to spawn new device technology, it does review innovations that others have generated, authorizing distribution only if statutory standards are satisfied. The statute directs the agency to apply balancing tests that allow

clearance if the benefits of device use sufficiently outweigh the risks. See, e.g., 21 U.S.C. 360c(a)(2)(C).

The FDA reviews devices under one of three clearance processes. *First*, the FDA regulates clinical experimentation with new devices through the investigational device exemption ("IDE") process. To obtain FDA approval for any clinical experiment involving significant risk to the subject, the sponsor must submit an IDE application containing detailed information about the device and a proposed experimental plan. The FDA then reviews and, if appropriate, approves the application, which authorizes distribution of the device solely for experimental use. See *id.* § 360j(g); 21 C.F.R. Pt. 812.

Second, the FDA evaluates some Class III devices under the "premarket approval" process before allowing marketing to the general public. This process applies to new technologies that are significantly different from devices already on the market and to additional Class III devices the FDA specifies by regulation. See 21 U.S.C. 360c(f)(1), 360e(b)(1). To obtain this authorization, the manufacturer submits a premarket approval application ("PMA") containing significant information about the device for FDA review. If clinical data and other information in the PMA demonstrate that the device's safety and effectiveness are reasonably assured, the FDA approves marketing. See *id.* § 360e(c), (d); 21 C.F.R. Pt. 814. The premarket approval process involves the most stringent regulatory review undertaken by the FDA. See Pet. App. 4a.

When Congress enacted the MDA, it could not impose PMA requirements on devices already on the market without immediately prohibiting distribution of a broad spectrum of valuable devices, thereby endangering those dependent on them. Under the MDA, Congress allowed marketing of these

"preamendment" devices to continue until the FDA could determine whether premarket approval was necessary to assure reasonable safety and effectiveness. See H.R. Rep. No. 808, 101st Cong., 2d Sess. 14 (1990). Congress also maintained the availability of preamendment devices by prohibiting the FDA from imposing PMA requirements before manufacturers had sufficient time to assemble the data necessary to satisfy those requirements. The statute therefore bars the FDA from imposing PMA requirements until 30 months after it assigns a device to Class III. 21 U.S.C. 351(f)(2)(B)(i); see H.R. No. 853, *supra*, at 42. The statute did not, however, dictate when (after this 30-month period) the FDA *must* require PMAs for Class III preamendment devices. Accordingly, the FDA regulates Class III preamendment devices under the broad substantive requirements and enforcement powers described above until it decides to impose PMA requirements by regulation. See 21 U.S.C. 360e(b).

Third, if a "postamendment" Class III device such as the Model 4011 is not subject to PMA requirements, the statute requires premarket review and clearance through the "510(k)" process.[4] This process is established by, and named after, Section 510(k) of the FDCA, 21 U.S.C. 360(k), under which manufacturers submit information about the device, including its design, to the FDA to obtain marketing authorization. The FDA uses this information to determine whether the device under review is "substantially equivalent" to a preamendment device that the agency has allowed to be marketed without an approved PMA. The substantial equivalence

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[4] The FDA also clears postamendment devices in Class II, and some in Class I, for marketing under the 510(k) process.

determination establishes that the device under review and the preamendment device have comparable safety and effectiveness. See, e.g., H.R. Rep. No. 853, *supra*, at 36. The FDA authorizes marketing if the devices are substantially equivalent and denies clearance if they are not. If the FDA clears the Class III device under the 510(k) process and later determines that it should be reviewed under the premarket approval process, it issues a regulation requiring PMAs. See 21 U.S.C. 360e(b).

B. This Litigation

In 1982, Medtronic filed a 510(k) submission with the FDA seeking clearance to market the Model 4011. The FDA requested additional information relating to the device's design, including explanations regarding proposed materials and the lead's structure and function. (R1-37-Exh. 1, at 3.) Following receipt of this information, the FDA authorized the lead for marketing. *Ibid.*

Plaintiff Lora Lohr is wholly dependent upon pacemaker technology for the proper functioning of her heart, described by her physician as "100 percent paced." (R1-28-12.) Mrs. Lohr was implanted with a Model 4011 in 1987 at the age of 27. (See R1-3-1.) Approximately four years after the implant, the Model 4011 allegedly ceased functioning effectively, and Mrs. Lohr's physician replaced it with a different manufacturer's lead. (See R1-3-2.) The second lead in turn was replaced approximately two years later with the lead she depends upon today. (R1-28-32, 33.)

Mrs. Lohr and her husband subsequently filed this suit in Florida state court, asserting claims of negligence, strict liability, and breach of implied warranty concerning an alleged pacemaker system failure attributed to the Model 4011. The action was removed to the United States District Court for the Middle District of Florida as a diversity of citizenship case.

The district court subsequently dismissed the implied warranty claim for failure to state a claim under Florida law. See Pet. App. 6a-7a, 1d.

Medtronic then moved for summary judgment on the ground that the express preemption provision of the FDCA, 21 U.S.C. 360k(a), preempted the remaining negligence and strict liability claims. Although the district court initially denied the motion, Pet. App. 1d, it granted reconsideration because of the Eleventh Circuit's decision in *Duncan* v. *Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994), which had affirmed the preemption of negligence and strict liability claims under the FDCA. The district court held that all of plaintiffs' claims were preempted and entered judgment for Medtronic. Pet. App. 1b.

C. The Court of Appeals Opinion

The Eleventh Circuit affirmed in part and reversed in part, holding that plaintiffs' claims alleging failure to warn and defective manufacture were preempted but that their defective design claims were not. The court based its analysis primarily upon the FDCA preemption provision and a comparison between state and federal requirements governing the Model 4011.

Citing this Court's opinion in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), the Eleventh Circuit held that common law actions were state "requirements" subject to preemption under Section 360k(a). See Pet. App. 11a. Specifically, the court of appeals held that plaintiffs' claims would create state "requirements" by asking a jury to determine how a reasonable manufacturer should design, manufacture, and provide warnings for the Model 4011. Pet. App. 25a, 30a, 32a.

The Eleventh Circuit then held that there are federal "requirements" within the language of Section 360k(a) that preempt plaintiffs' claims involving allegations of failure to warn and defective manufacture. However, the Eleventh Circuit also held that plaintiffs' claims relating to device design are not preempted, because the court could not identify any preemptive federal design "requirement" that met its construction of Section 360k(a). Pet. App. 28a-29a. The court suggested that there could be no express preemption of design claims unless there were substantive federal requirements that "set the standard" for the device's design. See Pet. App. 25a. Concluding that the FDCA does not specify such design standards, the court held that the plaintiffs' design claims are not expressly preempted. Pet. App. 29a. The Eleventh Circuit also held that the design claims are not impliedly preempted, because it could not identify an actual conflict between state and federal law. See Pet. App. 10a n.5. The Eleventh Circuit's holding therefore preserved certain claims from express and implied preemption even though they would expose Medtronic to state law liability for marketing a device design that the FDA had authorized under federal law.

INTRODUCTION AND SUMMARY OF ARGUMENT

The FDCA preempts plaintiffs' common law claims relating to the design of the Model 4011. The FDCA preemption provision prohibits state requirements relating to device safety and effectiveness or device design if they are "different from, or in addition to," any applicable federal requirement. Preemption analysis therefore entails identifying the federal and state requirements encompassed by the preemption provision and comparing them to determine whether the state requirements are different from, or in addition to, the federal requirements. If so, they are preempted.

I. The FDA's 510(k) premarket clearance process imposes a variety of "requirements" that trigger preemption under the FDCA. That process imposes two major types of federal requirements relating to the design and safety and effectiveness of the Model 4011. First, the FDCA establishes requirements that grant the FDA power to authorize marketing. These requirements include prohibitions on marketing without FDA clearance; submission requirements dictating the information about the device (including its design) the FDA will review; and the "substantial equivalence" requirement, which defines the devices the FDA may clear for marketing.

Second, after marketing begins, additional federal requirements prohibit changes in the FDA-authorized design that could significantly affect safety or effectiveness without further FDA clearance. These requirements effectively prevent the manufacturer from changing the design reviewed and cleared by the FDA.

The FDA has the power to impose a third possible type of requirement—PMA approval—on devices such as the Model 4011. The FDA has elected not to exercise that power for pacemaker leads, indicating that other safeguards are adequate to ensure their safety and effectiveness.

The preemption provision encompasses all of these federal 510(k) requirements. Under that provision, "*any*" federal requirement preempts defined categories of state requirements as long as it is "applicable to the device." The 510(k) requirements come within the plain meaning of this statutory language. In addition, two other FDCA sections use the same terminology, explicitly referring to Section 510 as imposing "requirements" that are "applicable to the device." Reading these sections together with the FDCA preemption provision

confirms that the 510(k) requirements preempt any state requirement that provision encompasses.

The Eleventh Circuit, however, held that the 510(k) requirements have *no* preemptive effect at all, because they do not dictate particular federal design standards on their face. This was error. The court of appeals bypassed the language of the FDCA preemption provision and premised its holding upon the FDA interpretative regulation set forth at 21 C.F.R. 808.1(d). The court instead should have applied the plain meaning of the statutory language. Furthermore, the regulation itself indicates that the 510(k) requirements are preemptive.

II. Plaintiffs' state common law claims also meet all of the statutory criteria requiring their preemption. The preemption provision applies to

(a) "*any requirement*"

(b) that a state or political subdivision "*establish*[*es*] *or continue*[*s*] *in effect*,"

(c) "*with respect to a device intended for human use*,"

(d) that "*relates* [i] *to the safety or effectiveness of the device or* [ii] *to any other matter included in a requirement applicable to the device*" under the FDCA, and

(e) that is "*different from, or in addition to*," "any" applicable FDCA "requirement" such as those imposed under Section 510(k).

(a) Under the statute's plain meaning, the duties imposed by plaintiffs' common law claims are state "requirements." Common law duties have as potent a regulatory effect as state legislative enactments, requiring manufacturers to modify conduct to avoid future liability. Furthermore, this Court's decision in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504

(1992), which held that common law claims were "requirements or prohibitions" preempted by the Public Health Cigarette Smoking Act of 1969, applies directly to this case. The language of the FDCA preemption provision is indistinguishable in relevant respects from the language of the statute at issue in *Cipollone*.

(b) Plaintiffs' common law design claims would allow a "state or political subdivision of a state" to "establish or continue in effect" state requirements. The requirements at issue are established by Florida state judges and juries, and they would continue in effect unless preempted.

(c) Plaintiffs' claims would establish state requirements "with respect to a device intended for human use." The ordinary meaning of the phrase "with respect to a device" applies to those claims, which allege that Medtronic should have marketed a device with a different design.

(d) The state law requirements that would be established by plaintiffs' claims "relate to the safety or effectiveness of the device." The duties underlying plaintiffs' claims relate fundamentally to both safety and effectiveness, because plaintiffs assert that the alleged failure of the device to continue operating properly endangered Mrs. Lohr. In addition, the state law requirements established by plaintiffs' claims would "relate to" device design, which is a "matter included in a requirement applicable to the device" under the FDCA.

(e) Plaintiffs' claims are preempted, because they would establish state requirements "different from, or in addition to," the federal 510(k) requirements. The premise of plaintiffs' claims is that Florida common law imposed a duty on Medtronic to market an allegedly safer and more effective device design than that cleared by the FDA under the 510(k) process. The 510(k) requirements therefore authorize marketing a device design that state law, through plaintiffs' claims,

would treat as defective. Furthermore, plaintiffs' claims would require Medtronic to change the device design in order to avoid future common law liability. The changes demanded by state law would conflict with federal 510(k) requirements barring design changes without FDA clearance. If Medtronic attempted to comply with the state law duty and immediately changed the design of the Model 4011, it would violate the federal 510(k) requirements and be subject to civil and criminal enforcement actions.

Beyond parsing of the statutory language, preemption is consistent with the purpose of the statute and sound public policy. Denying preemption would undermine Congress's decision that the responsibility for regulating device design falls within the FDA's expert judgment. Preservation of state design claims also would create a potential quagmire of inconsistent state requirements, often defined and imposed years after marketing clearance. Congress enacted the FDCA preemption provision for the purpose of prohibiting these restrictions, which Congress recognized could stifle innovation of new life-enhancing devices and interrupt continued nationwide availability of existing device therapies such as the one on which Mrs. Lohr depends. This Court therefore should reverse in part the judgment of the Eleventh Circuit and hold that the FDCA preempts plaintiffs' state common law design claims.

ARGUMENT

THE FDCA PREEMPTS PLAINTIFFS' STATE COMMON LAW DESIGN CLAIMS

The basis for federal preemption is the Supremacy Clause of the United States Constitution, which provides that "the Laws of the United States * * * shall be the supreme Law of the Land." U.S. Const. Art. VI, Cl. 2. Under that Clause, "state law that conflicts with federal law is 'without effect.' "

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland* v. *Louisiana*, 451 U.S. 725, 746 (1981)). In any preemption analysis, "[t]he purpose of Congress is the ultimate touchstone." *Gade* v. *National Solid Wastes Management Ass'n*, 505 U.S. 88, 96 (1992) (quoting *Malone* v. *White Motor Corp.*, 435 U.S. 497, 504 (1978)). Congress's intent to preempt state law "may be 'explicitly stated in the [federal] statute's language or implicitly contained in its structure and purpose.' " *Cipollone*, 505 U.S. at 516 (quoting *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Thus, "[t]o discern Congress' intent [a court should] examine the explicit statutory language and the structure and purpose of the statute." *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 138 (1990).

The language and structure of the FDCA express Congress's intent to preempt state common law claims relating to the design of Class III medical devices (such as the Model 4011) that the FDA has authorized for marketing under the 510(k) process. As explained below, the FDCA establishes a variety of "requirement[s] applicable to" the Model 4011 (including requirements relating to device design and safety and effectiveness). In addition, plaintiffs' common law design claims, if permitted to proceed, would "establish or continue in effect" state "requirements" that "relate[] to the safety or effectiveness of the device or to any other matter included in a [federal] requirement." And those state requirements would be "different from, or in addition to," the extensive federal requirements applicable to the Model 4011. The statute's exemption provision, moreover, provides further evidence that Congress intended broad preemption while vesting the FDA with authority to grant case-by-case exceptions. Finally, preemption of plaintiffs' design claims is fully consistent with Congress's objectives—it preserves incentives for manufacturers to bring new technologies onto the

market and continue improving existing devices but does not impair the FDA's broad authority to regulate device safety and effectiveness.

A. The FDCA Establishes Substantial Requirements Concerning the Design of the Model 4011

Preemption analysis begins with the plain wording of the statute, which "necessarily contains the best evidence of Congress' pre-emptive intent," *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993), because it is assumed that the ordinary meaning of statutory language accurately expresses the legislative purpose. *Morales* v. *TWA, Inc.*, 504 U.S. 374, 383 (1992). The FDCA preemption provision's sweeping language states that "any requirement applicable under [the FDCA] to the device" preempts different or additional state requirements. 21 U.S.C. 360k(a)(1). The broad term "requirement" encompasses both federal statutory and regulatory provisions. Furthermore, *any* requirement under the FDCA is preemptive as long as it is "applicable to the device." In this case, the preemptive federal requirements are those imposed by the 510(k) process.

Despite the broad language of the statute, the Eleventh Circuit appears to have concluded that federal requirements must explicitly govern device safety to preempt plaintiffs' claims. The court of appeals denied preemption of the strict liability design claim because it believed that the 510(k) requirements, among others, did not "impose specific safety requirements" on the Model 4011. Pet. App. 35a. Similarly, holding that the 510(k) requirements did not preempt the negligent design claim, the court of appeals emphasized its belief that "[t]he 510(k) process is focused on equivalence, not safety." Pet. App. 27a.

The Eleventh Circuit's ruling is based on a misunderstanding of both the federal statute and the role played by the

FDA. The statute does not limit preemption to federal safety requirements: "*any*" FDCA requirement applicable to the device preempts additional or different state law. Furthermore, device safety is always implicated in the FDA's substantial equivalence determination. To envision the FDA as entirely agnostic on the question of the Model 4011's safety and effectiveness, as the Eleventh Circuit did, is quite wrong. The discussion below explains why the 510(k) requirements assure that the safety and effectiveness of the Model 4011 are comparable to a preamendment device.

The Eleventh Circuit also thought it pivotal that the MDA did not "establish[] specific requirements that apply to the design of" the device in question. Pet. App. 25a. Again the Eleventh Circuit was doubly wrong. The statute's plain language—"any requirement applicable * * * to the device"—is inconsistent with the conclusion that a "specific requirement[]" applicable "to the design" is necessary for preemption; and in any event, the 510(k) requirements actually are intimately related to device design, as the discussion below explains.

1. The 510(k) Requirements Empower the FDA to Authorize or Deny Marketing Clearance

The 510(k) requirements grant the FDA power to authorize or deny marketing of Class III devices such as the Model 4011. At the time the agency cleared the Model 4011, the FDCA prohibited manufacturers from marketing without filing a 510(k) submission seeking the FDA's permission; the agency had authority to seek civil and criminal sanctions

against manufacturers that violated this requirement.[5] The FDA also could initiate enforcement actions against manufacturers that marketed a device despite agency denial of 510(k) clearance.[6] Finally, if a 510(k) submission was pending at the FDA, the statute prohibited the manufacturer from marketing for 90 days unless the FDA granted clearance sooner.[7]

The FDA granted 510(k) clearance for the Model 4011 before this 90-day period expired, authorizing immediate marketing in a letter that stated:

> We have reviewed your premarket notification submission and have found the device to be substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. *You may, therefore, market your device* subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act).

(R1-37-Exh. A to Exh. 1) (emphasis added); see also 21 C.F.R. 870.3(a) (cardiovascular device that has been found

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[5] See 21 U.S.C. 352(o), 331-333 (1982); *United States* v. *An Article of Device*, 607 F. Supp. 990 (W.D. Mich. 1985) (seizure action premised upon failure to file 510(k) submission).

[6] The FDA denies clearance when it determines that the device under review is not "substantially equivalent" to a preamendment device. Devices that are not substantially equivalent are, by definition, Class III devices subject to PMA requirements. 21 U.S.C. 360c(f)(1)(A); 21 C.F.R. 870.3(b). Marketing a device without a required PMA renders it adulterated in violation of the FDCA. See 21 U.S.C. 351(f)(1)(B).

[7] 21 U.S.C. 360(k), 352(o); 21 C.F.R. 807.81(a).

substantially equivalent "may be commercially marketed" without an approved PMA).[8]

Even after it authorizes marketing, the FDA controls continued distribution of devices through the 510(k) requirements. The FDA consistently has taken the position that it has the authority to rescind 510(k) clearance. For example, under its fraud policy, the agency will rescind 510(k) clearance if there are fraudulent data in the submission documents. See 56 Fed. Reg. 46,191, 46,193, 46,197 (Sept. 10, 1991). Since 1988, the FDA has acted to rescind approximately seventy-five 510(k) clearances. Interim Response to Citizen Petition, FDA Docket No. 94A-0388 (Sept. 11, 1995). These rescission actions underscore the agency's broad authority to restrict market access under the 510(k) requirements.[9]

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[8] In the 1990 amendments to the FDCA, Congress added the requirement of an administrative order to the 510(k) clearance process. Since then, marketing is barred until the FDA "by order" has found substantial equivalence. 21 U.S.C. 360c(i)(1)(A). The legislative history of the 1990 amendments indicates that the addition of an administrative order was not intended to change the legal effect of the FDA's prior practice. S. Rep. No. 513, 101st Cong., 2d Sess. 19 (1990).

[9] Although the FDA affirmatively authorizes marketing through the 510(k) process, the agency also takes the position that 510(k) clearance does not denote official "approval" of the device. 21 C.F.R. 807.97. The FDA's position is consistent with other requirements in the statute and regulations barring manufacturers from advertising FDA status, even for PMA "approved" devices. The FDA's sensitivity is manifest in requirements barring representations that *either* 510(k) *or* PMA devices are "FDA-approved." Compare 21 C.F.R. 807.97 (representation that 510(k) clearance is FDA approval constitutes misbranding) with 21 U.S.C. 331(*l*) (representation in labeling or advertising that PMA device has premarket approval constitutes a prohibited act); see also 21 C.F.R. 807.39 (barring description of facility registration so as to connote

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a. Federal Requirements to Submit Information Justifying Premarket Clearance

To obtain 510(k) clearance, manufacturers must comply with federal requirements to submit significant information about the device to the FDA. The manufacturer must provide all information the FDA deems necessary to determine substantial equivalence between the device under review and a preamendment or "predicate" device. Much of this information relates to device design, because the demonstration of substantial equivalence necessarily requires a comparison of the technological characteristics of the two devices. See 21 U.S.C. 360c(i)(1)(A). The information submitted also relates to safety and effectiveness, because the substantial equivalence determination requires a judgment relating to the devices' comparative safety and effectiveness. See pp. 23-27, *infra*.

Some information, such as proposed device labeling, is specifically required for all devices under 510(k) review. See 21 C.F.R. 807.87(e). Other information is required when the features of a particular device make it relevant to the substantial equivalence determination. This information may include photographs or engineering drawings, information regarding materials, design considerations, and energy used or

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approval). Particular terminology aside, the fact that 510(k) clearance is not characterized as an "approval" does not affect the preemptive force of the 510(k) requirements. The FDCA preemption provision draws no distinction between PMA and 510(k) devices, basing preemption on applicable federal "requirements" rather than on FDA "approval."

delivered by the device, and a description of its operational principles. *Id.* § 807.87(e), (f).

After it receives the 510(k) submission, the FDA may impose other requirements pursuant to 21 C.F.R. 807.87(k), which gives the agency authority to make specific requests for any additional data it deems relevant to the substantial equivalence determination. For example, after it received the 510(k) submission for the Model 4011, the FDA requested and received additional information concerning the lead's design (including explanations regarding proposed materials and the structure and function of the lead) before it would clear the device for marketing. (R1-37-Exh. 1, at 3.) An FDA request for additional information under Section 807.87(k) is a concrete requirement that must be complied with, because the agency deems the 510(k) submission withdrawn if the manufacturer does not honor the request within 30 days. *Id.* § 807.87(k).

b. Federal Requirements Governing the Substantial Equivalence Determination

After the FDA receives the information described above, it determines whether the device under review is substantially equivalent to a preamendment device. A device like the Model 4011 can be marketed only if the requirement of substantial equivalence is satisfied; absent substantial equivalence, the FDCA bars marketing without an approved PMA. See 21 U.S.C. 360c(f)(1), 360e(a).

The substantial equivalence determination is integrally related to the designs of the device under review and its preamendment predicate device and to the comparative safety and effectiveness of the two devices. At the time the FDA cleared the Model 4011 for marketing, the FDCA prescribed the substantial equivalence requirement without explicitly defining it. See 21 U.S.C. 360c(f)(1)(A) (1982). However,

the legislative history of the MDA indicates that Congress intended the substantial equivalence determination to ensure that devices marketed for the first time after its enactment are as safe and effective as preamendment devices. According to the House Report, devices are substantially equivalent if "differences between a new device and a marketed device do not relate to safety and effectiveness." H.R. Rep. No. 853, *supra*, at 36. The House Report also specifically indicates that differences in design are among the issues that can affect substantial equivalence. *Id.*

Consistent with Congress's mandate, the FDA has administered the 510(k) clearance process to ensure that the device under review (including its design) is as safe and effective as the predicate preamendment device. In 1983, shortly after it cleared the Model 4011 for marketing, the FDA described its substantial equivalence review process in an agency response to a GAO report as follows:

> We also believe FDA is applying the "substantial equivalency" test in a manner consistent with Congressional intent, though Congress' instructions are not explicit on the interpretation of this term. *FDA reviews premarket notifications to determine if the differences between pre- and post-Amendments devices are material to safety and effectiveness.* If there are no differences or if the differences do not present unanswered questions of safety and effectiveness, FDA finds post-Amendments devices "substantially equivalent" to their pre-Amendments predecessors. If the differences do present unanswered questions of safety and effectiveness, or if adequate comparisons cannot be made due to unique, new indications, then FDA finds post-Amendments devices "not substantially equivalent."

U.S. General Accounting Office, Pub. No. GAO/HRD-83-53, Federal Regulation of Medical Devices—Problems Still to Be Overcome 76 (Sept. 30, 1983) (emphasis added).

In 1990, Congress amended the FDCA to codify the FDA's long-standing interpretation of the term "substantial equivalence." See H.R. Rep. No. 808, 101st Cong., 2d Sess. 24 (1990); S. Rep. No. 513, 101st Cong., 2d Sess. 28 (1990). The 1990 amendments set forth two tests for substantial equivalence. The first refers explicitly to comparable safety and effectiveness, authorizing 510(k) clearance if a device with the same intended use as the predicate device (1) has different technological characteristics; (2) is as safe and effective as the predicate device; and (3) does not raise different questions of safety and effectiveness. See 21 U.S.C. 360c(i)(1)(A)(ii). Under this test, differences in technological characteristics relevant to the substantial equivalence determination include differences in device design. See 21 C.F.R. 807.100(b)(2)(ii)(A).

The second test authorizes 510(k) clearance if a device has the same intended use and technological characteristics as the predicate device. See 21 U.S.C. 360c(i)(1)(A)(i). This test also necessarily focuses on device design, which is the essential technological characteristic of any device. In addition, the second test assures comparable safety and effectiveness, although the statutory language does not explicitly refer to these factors. Read together with the requirements of the first test, the second test presumes that if the technological characteristics of two devices are the same, their safety and effectiveness will, by definition, be comparable. It is only if technological characteristics are different that comparable safety and effectiveness are uncertain.

The legislative history confirms this interpretation of the second test. The Senate Report for the 1990 amendments

states that a demonstration that devices have the same technologies is a demonstration that their safety and effectiveness is comparable:

> Generally speaking, a device is substantially equivalent to its predicate device if it has the same intended use, and is as safe and effective, as the predicate device. *The determination of comparable safety and effectiveness is at times easy, where the newer device and its predicate use the same technologies.* More difficult judgments occur when the technologies of the devices differ. In this latter situation, the FDA will not make a substantial equivalance [sic] determination without data, including clinical data, that demonstrates comparable safety and effectiveness.

S. Rep. No. 513, *supra*, at 28 (emphasis added).[10]

The FDA has confirmed since the 1990 amendments that its administration of the 510(k) clearance process *always* has required a finding of comparable safety and effectiveness:

> The legislative history of the 1990 amendments states Congress' express intent to codify FDA's interpretation of the term "substantial equivalence," including the agency's determination that *substantial equivalence requires a finding of comparable safety and effectiveness.*

59 Fed. Reg. 64,287, 64,288 (Dec. 14, 1994) (emphasis

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[10] The Eleventh Circuit erroneously concluded that the substantial equivalence determination could be made without regard to safety and effectiveness if the technological characteristics of the two devices were the same. See Pet. App. 26a.

added) (citation omitted).[11]

The Eleventh Circuit therefore erred when it concluded that "while a substantial equivalence finding can be a finding of safety and effectiveness, there is no way to tell whether a given substantial equivalence finding is a finding of safety and effectiveness." Pet. App. 26a. Although it does not purport to guarantee safety and effectiveness, the 510(k) process ensures that new devices will be as safe and effective as their preamendment predicates.

2. The 510(k) Requirements Impose Substantial Restrictions on Changes in Device Design

The 510(k) premarket clearance only authorizes the marketing of a device with the particular design submitted to, and reviewed by, the FDA. Once a device is cleared for marketing through the 510(k) process, the manufacturer may not change the device design in a manner that could significantly affect safety or effectiveness without an additional 510(k) clearance by the FDA:

> A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process [requires filing a 510(k) submission seeking FDA clearance].

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[11] Since the 1990 amendments, the FDA has promulgated new regulations expanding the safety and effectiveness information that must be included in 510(k) submissions for Class III devices. See, e.g., 21 C.F.R. 807.94 (requirement to include bibliography of safety and effectiveness data in 510(k) submission).

21 C.F.R. 807.81(a)(3)(i).[12] This prohibition on changes applies regardless of whether the manufacturer believes that they would decrease or increase device safety or effectiveness.[13] In *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), petition for cert. pending, No. 95-1010, the Fourth Circuit cogently explained the effect of these 510(k) requirements as follows:

> The FDA's determination that [the manufacturer's] prosthesis is substantially equivalent to those previously marketed thus binds [the manufacturer] to its representations to the FDA; for all intents and purposes, [the manufacturer] is required to continue to design, manufacture, and label the device as proposed in its original 510(k) Notification.

Id. at 399-400.

3. The FDA Has Not Invoked Its Authority to Impose PMA Requirements

Relying for premarket clearance on the 510(k) requirements described above, the FDA has not invoked its authority to bar marketing of the Model 4011 without PMA approval. The FDCA does give the FDA authority to impose PMA requirements for Class III devices, such as the Model 4011, previously cleared for marketing under the 510(k) process.

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[12] 21 C.F.R. 807.87(g) requires that the 510(k) submission relating to a proposed product change "must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device."

[13] See, e.g., 42 Fed. Reg. 42,520, 42,522 (Aug. 23, 1977) (preamble to 510(k) regulation).

When it decides to require this more extensive safety and effectiveness review, the FDA calls for PMAs by regulations that specifically describe the type of device that will be subject to premarket approval. See 21 U.S.C. 360e(b).[14] The statute dictates the timing of this FDA action, barring imposition of PMA requirements until 30 months after the agency assigns a device to Class III. 21 U.S.C. 351(f)(2)(B)(i). In its discretion, the FDA frequently has waited much longer than 30 months after classification to call for PMAs, regulating safety and effectiveness through the 510(k) process and its other broad powers until it decides that PMAs are necessary to assure reasonable safety and effectiveness. See, e.g., 60 Fed. Reg. 41,984 (Aug. 14, 1995). Although the FDA classified pacemaker leads such as the Model 4011 as Class III devices in 1980, it never has required PMAs for such products. See 21 C.F.R. 870.3680(b), (c).

The FDA's decision not to impose PMA requirements on the Model 4011 and other pacemaker leads indicates its apparent satisfaction with the degree of regulatory control the 510(k) requirements provide.[15] In fact, it appears the FDA

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[14] The regulation calling for PMAs applies both to the device cleared through the 510(k) process and to the preamendment predicate device. See 21 U.S.C. 360e(b)(1).

[15] It also appears that the FDA is satisfied regulating preamendment pacemaker leads without requiring PMA approval, because it has not exercised its authority to impose PMA requirements on those devices. The FDA regulates preamendment Class III devices under its substantive safety and effectiveness requirements and its broad enforcement powers to remove unsafe and ineffective devices from the market, retaining the authority to require PMAs if necessary. See pp. 8-9 *supra*. The Eleventh Circuit ignored these extensive requirements, using the term

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has concluded that PMAs may never be necessary to provide reasonable assurance of safety and effectiveness for the Model 4011 and other pacemaker leads. When it enacted the 1990 amendments, Congress imposed a timetable on the FDA for resolving whether to require PMAs for Class III devices. If the agency did not find PMA requirements necessary to provide reasonable assurance of safety and effectiveness, the amendments mandated it to propose reclassification to Class I or Class II, because devices in those classes, by definition, are never subject to PMA requirements. See 21 U.S.C. 360e(i)(2). Pursuant to this statutory mandate under the 1990 amendments, the FDA has indicated that there is a "high potential" that it will reclassify pacemaker leads to Class II, thereby barring future imposition of PMA requirements. 60 Fed. Reg. 41,986, 41,987-41,988 (Aug. 14, 1995) (notice regarding cardiovascular permanent pacemaker electrodes).

B. Federal Requirements Imposed Through the 510(k) Process Have Preemptive Effect

1. Federal Requirements Imposed Through the 510(k) Process Are "Applicable to the Device"

Section 360k(a) states that "*any* requirement applicable under this [Act] to the device" preempts certain defined state requirements. 21 U.S.C. 360k(a) (emphasis added). This plain language encompasses the federal 510(k) requirements imposed on the Model 4011. Those requirements "apply to"

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"grandfathering" pejoratively to suggest that preamendment devices entirely escape FDA safety and effectiveness regulation. See, e.g., Pet App. 4a, 5a.

devices such as the Model 4011, because they restrict marketable device designs to those that are substantially equivalent to preamendment devices, require FDA authorization for marketing the design, and then prohibit changes in the FDA-authorized design without further agency clearance.

The language of two other FDCA provisions confirms that Section 510(k) establishes federal "requirements" that are "applicable to" the device within the meaning of Section 360k(a). First, 21 U.S.C. 360c(d)(2)(A) authorizes the FDA to promulgate regulations that exempt certain Class I devices from 510(k) clearance and other federal requirements.[16] This provision establishes that Section 510 imposes "requirements" that are applicable to the device unless the FDA promulgates an exempting regulation that makes them "inapplicable." Section 360c(d)(2)(A) requires the FDA's exempting regulation to prescribe which of the "*requirements* of section [510] * * * shall *not apply to* the device." 21 U.S.C. 360c(d)(2)(A) (emphasis added). Under the same Section, a regulation that "makes a requirement of section [510] * * * inapplicable to a device" must be accompanied by an FDA explanation "for making such requirement inapplicable." Because identical terms in different sections of the same act are construed to have the same meaning, see, e.g., *Estate of Cowart* v. *Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992), Section 360c(d)(2)(A) confirms that the 510(k) process imposes "requirements" that are "applicable to the device" within the meaning of the FDCA preemption provision.

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[16] Under this statutory provision, the FDA has exempted over 500 Class I devices from the 510(k) process. See 21 C.F.R. Pts. 862-892.

Second, the language of 21 U.S.C. 360j(a) also confirms that the 510(k) process imposes federal "requirements" that are "applicable to the device." Under Section 360j(a), "[a]ny requirement authorized by or under section * * * [510] * * * applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed" by certain FDA actions. 21 U.S.C. 360j(a). Under the same Section, "any requirement established by or under section * * * [510] * * * which is inconsistent with" certain other federal requirements "shall not apply to the device." Section 360j(a) therefore unequivocally establishes that 510(k) requirements are "applicable to the device" unless the FDA changes their applicability or other statutory provisions not relevant to this case conflict with 510(k) requirements.[17] The language of Section 360j(a) therefore compels the conclusion that the 510(k) process establishes federal "requirements" that are "applicable to the device," and therefore are preemptive, under Section 360k(a).

2. Federal Requirements Imposed Through the 510(k) Process Need Not Prescribe Particular Substantive Design Standards to Preempt State Requirements

Despite the broad language of the FDCA preemption provision, the Eleventh Circuit held that plaintiffs' design

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[17] The particular FDA actions and requirements that may affect applicability of 510(k) requirements concern Sections 513, 514, 515, and 520(g) of the FDCA, 21 U.S.C. 360c, 360d, 360e, 360j(g). These FDCA Sections authorize the FDA to reclassify devices and adopt performance standards for Class II devices, premarket approval requirements for Class III devices, and IDE requirements for investigational devices. None of these provisions applies in this case.

claims were not preempted, because there were no federal requirements that "set the standard" for device design. See Pet. App. 25a. The court erred, because the statutory language provides no basis for limiting preemption to situations in which federal requirements dictate particular design standards. Under Section 360k(a), "any requirement" under the FDCA has preemptive effect if it is "applicable to the device."

The Eleventh Circuit's holding that there are no preemptive federal design requirements therefore is insupportable. The court of appeals explicitly acknowledged that it was rejecting a "literal reading of section 360k(a)," which it believed would raise a "host of problems" by inferring "broad preemptive intent." Pet. App. 16a. In doing so, the Eleventh Circuit refused to follow this Court's rulings to the effect that the plain wording of the statute "necessarily contains the best evidence of Congress' pre-emptive intent," *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993).

Rather than relying on the ordinary meaning of Section 360k(a), the court of appeals found the following FDA interpretative regulation controlling:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. 808.1(d). Although it acknowledged that "a precise definition of what the FDA means by 'specific requirements' " is not possible, Pet. App. 21a, the Eleventh Circuit

relied on that phrase to conclude that there were no preemptive federal design requirements.

Even if it had been appropriate to bypass the express statutory language (which mandates preemption) in favor of this agency interpretation, the FDA's regulation does not, on its face, limit preemption of state-imposed design requirements in the manner claimed by the Eleventh Circuit. Although it adds the modifier "specific" (which is found nowhere in the statutory language) to the FDCA term "requirement," the FDA's regulation does not state that particular federal design standards are a prerequisite for preemption. Instead, the regulation indicates that as long as the "specific [federal] requirements" are "applicable to a particular device," they preempt state law. The analysis at pages 22-28 *supra* demonstrates that the 510(k) process unquestionably imposes specific design requirements that are applicable to the particular pacemaker lead at issue in this case. Therefore, construed consistently with the FDCA preemption provision, the FDA's interpretative regulation compels the conclusion that these specific federal design requirements have preemptive effect.

The errors in the Eleventh Circuit's analysis are made evident by the astounding effects its ruling would have. The holding would deny preemption of virtually all state design requirements applicable to Class III 510(k) devices, regardless of whether they were imposed through common law claims or legislative enactments. As a result, state legislatures and regulators could enact their own design standards, even if they conflicted with the particular device designs the FDA authorized for marketing. Furthermore, juries could conclude that it is "negligent" or otherwise in violation of state common law to use the federally authorized design.

For example, under the Eleventh Circuit's holding, states could prohibit (or juries could deem "negligent") the use of particular materials in the design of pacemaker leads, even though the FDA authorized marketing of leads designed with those materials. To make matters worse, different states, through legislation or common law decisionmaking, could adopt contradictory design standards, with some requiring use of the very same materials that others prohibited. It would be wholly inconsistent with the statutory language and congressional intent for the FDCA to preserve state design requirements that would impose conflicting standards or bar a manufacturer from marketing a design authorized under federal law.

Furthermore, if the 510(k) requirements were not preemptive, the states could impose different design requirements through their own premarket clearance processes. For example, state legislatures could adopt less restrictive versions of the federal 510(k) requirements, authorizing marketing of device designs that the federal requirements would prohibit. Conversely, states could enact statutes barring marketing of all Class III devices unless their designs had been approved through a state PMA process. These statutes would conflict directly with federal 510(k) requirements, which authorize marketing of some Class III devices (including the Model 4011) without an approved PMA. The FDCA preemption provision obviously is intended to bar these types of inconsistent state requirements.[18] This Court therefore should

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[18] The House Committee report for the MDA explicitly notes that a California statute establishing state PMA requirements was preempted unless and until the FDA granted an exemption from preemption. H.R. Rep. No. 853, 94th Cong., 2d Sess. 45-46 (1976).

reject the Eleventh Circuit's holding and conclude that the 510(k) process imposes federal design "requirements" within the meaning of the FDCA preemption provision.

C. The FDCA Preempts Plaintiffs' State Common Law Design Claims

Plaintiffs' state common law claims meet all of the statutory criteria requiring their preemption. The preemption provision applies to

(a) "*any requirement*"

(b) that a state or political subdivision "*establish*[*es*] *or continue*[*s*] *in effect*,"

(c) "*with respect to a device intended for human use*,"

(d) that "*relates* [i] *to the safety or effectiveness of the device or* [ii] *to any other matter included in a requirement applicable to the device*" under the FDCA, and

(e) that is "*different from, or in addition to*," "any" applicable FDCA "requirement" such as those imposed under Section 510(k). See 21 U.S.C. 360k(a) (emphasis added).

The analysis below explains why plaintiffs' state common law claims fall comfortably within each of these phrases.

1. Plaintiffs' Design Claims Would Establish State "Requirements"

Plaintiffs' common law design claims would establish state "requirements" within the meaning of Section 360k(a). Plaintiff's claims are premised upon the theory that Florida common law required Medtronic to provide a different design, allegedly safer and more effective, than the one cleared for marketing under the 510(k) process. Just as a state statute or regulation could mandate a different design, plaintiffs'

claims invoke the coercive power of the State of Florida to impose substantive design requirements.

In *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 522 (1992), a plurality of this Court explained that common law damages actions "are premised on the existence of a legal duty," and that "it is the essence of the common-law to enforce duties." This Court also has recognized that by imposing legal duties, common law claims assert regulatory obligations under state law that are as potent as a positive state enactment:

> [State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.

San Diego Bldg. Trades Council v. *Garmon*, 359 U.S. 236, 247 (1959); see also *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 142 (1990) (state common law claims could require "the tailoring of [pension] plans and employer conduct to the peculiarities of the law of each jurisdiction"). The plain meaning of the FDCA phrase "any requirement" easily encompasses the state law duties imposed by plaintiffs' design claims.[19]

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[19] The court below and eight other circuits have concluded that the FDCA preempts common law claims. *Lohr*, Pet. App. at 11a; *King* v. *Collagen Corp.*, 983 F.2d 1130 (1st Cir.), cert. denied, 114 S. Ct. 84 (1993); *Becker* v. *Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995); *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994); *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), petition for cert. pending, No. 95-1010; *Stamps* v. *Collagen Corp.*, 984 F.2d 1416 (5th Cir.), cert. denied, 114 S. Ct. 86 (1993);

(Footnote cont'd on next page)

Furthermore, this Court recently ruled that statutory language substantially identical to the FDCA preemption provision encompasses state common law claims. In *Cipollone*, the Court construed the following express preemption provision in the Public Health Cigarette Smoking Act of 1969:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

15 U.S.C. 1334(b). Six Justices concluded that the term "requirement or prohibition" in this provision encompassed state common law claims. 505 U.S. at 521-22 (opinion of Stevens, J.); *id.* at 548-49 (opinion of Scalia, J.). The plurality opinion of Justice Stevens explained the holding as follows:

> [Petitioner] argues that common-law damages actions do not impose "requirement[s] or prohibition[s]" and that Congress intended only to trump "state statute[s], injunction[s], or executive pronouncement[s]." We disagree; such an analysis is at odds both with the plain words of the 1969 Act and with the general understanding of common-law damages actions. *The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common*

(Footnote cont'd from previous page.)

Martin v. *Telectronics Pacing Sys., Inc.*, 70 F.3d 39 (6th Cir. 1995); *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), cert. denied, 505 U.S. 917 (1992); *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), cert. denied, 115 S. Ct. 2614 (1995). But see *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995).

> *law; to the contrary, those words easily encompass obligations that take the form of common-law rules.*

Id. at 521 (emphasis added) (footnote omitted); cf. *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993) (state common law claims encompassed by preemption provision barring state "law, rule, regulation, order, or standard relating to railroad safety").

The *Cipollone* holding applies directly to this case, because the FDCA preemption language is in relevant respects "indistinguishable from the act at issue in *Cipollone*." *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540, 543 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994). The FDCA preempts state "requirement[s]," and the 1969 Cigarette Act construed in *Cipollone* preempts state "requirement[s] or prohibition[s]." The language differences between the two statutes are not material, because both phrases are properly interpreted as referring to the same legal duties. Given the holding in *Cipollone*, the conclusion is inescapable that state common law claims are "requirements" within the meaning of the FDCA preemption provision.[20]

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[20] Although reference to agency interpretations is unnecessary when, as in this case, the statutory language is clear, a portion of the FDA's interpretative regulation is consistent with the statutory language encompassing preemption of common law claims. According to the regulation, the FDCA preemption provision "prescribes a general rule" preempting certain defined state requirements "(whether established by statute, ordinance, regulation, or *court decision*)." 21 C.F.R. 808.1(b) (emphasis added).

2. Plaintiffs' Claims Would Allow a "State or Political Subdivision of a State" to "Establish or Continue in Effect" Requirements

The FDCA preemption provision also applies to plaintiffs' claims, because they would allow a "State or political subdivision of a State" to "establish or continue in effect" requirements through those claims. On its face, the term "State or political subdivision of a State" includes all organs of state government, including the judicial branch. See, e.g., *Ex parte Virginia*, 100 U.S. 339, 347 (1880) ("A State acts by its legislative, its executive, or its judicial authorities."); *Edmonson* v. *Leesville Concrete Co.*, 500 U.S. 614, 624 (1991) (jury is "quintessential governmental body"). Because the requirements plaintiffs seek to impose on Medtronic would be established by Florida state judges and juries, they come within the FDCA preemption provision.

Furthermore, the phrase "establish or continue in effect" is terminology wholly consistent with common law claims. These claims would enable Florida judges and juries to "establish" duties regarding design by requiring Medtronic to market a different design than the one authorized by the 510(k) process. In addition, consistent with the statute's plain meaning, those requirements would be "continue[d] in effect" through plaintiffs' claims unless preempted by the FDCA.

In *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658 (1993), this Court affirmed preemption of certain state common law claims, because the applicable preemption provision barred "[a] State" from "adopt[ing] or continu[ing] in force" certain railroad safety standards. *Id.* at 662 & n.2. The FDCA language is indistinguishable in relevant respects from that of the statute in *Easterwood*, and this Court similarly should construe it to bar plaintiffs' common law claims.

3. Plaintiffs' Claims Would Establish State Requirements "With Respect to a Device Intended for Human Use"

The FDCA preemption provision also applies to plaintiffs' common law claims, because they would establish state requirements "with respect to a device intended for human use." The ordinary meaning of the phrase "with respect to a device" clearly applies to those claims, which allege that Medtronic should be required to market a medical device with a different design. Pacemaker leads are "intended for human use" and were so used in this case. Just as common law claims "with respect to" advertising and promotion of cigarettes were preempted in *Cipollone*, 504 U.S. at 524 (opinion of Stevens, J.); *id.* at 544 (opinion of Scalia, J.), plaintiffs' claims come within the FDCA preemption provision.

4. The State Law Requirements Advanced by Plaintiffs' Claims Would "Relate[] to the Safety or Effectiveness of the Device or to Any Other Matter Included in a Requirement Applicable to the Device Under" the FDCA

Subsection (2) of Section 360k(a) states a disjunctive test for the subjects a state "requirement" must "relate to" before it will be preempted. Plaintiffs' claims are preempted under either prong of that test.

a. The State Law Requirements Advanced by Plaintiffs' Claims Would "Relate[] to the Safety or Effectiveness of the Device"

Without question, plaintiffs' common law design claims "relate to the safety or effectiveness of the device" within the plain meaning of the FDCA preemption provision. Plaintiffs' design claims are premised upon the assertion that the Model

4011 design was not sufficiently safe or effective. Plaintiffs' negligent design claim asserts violation of a Florida common law duty to design the device with reasonable care, so that the device would be reasonably safe for use in a foreseeable manner. See, e.g., *Witt* v. *Norfe, Inc.*, 725 F.2d 1277, 1278 (11th Cir. 1984). Plaintiffs' strict liability claim asserts violation of a Florida duty to design the device so that it was not in a defective condition unreasonably dangerous to foreseeable users and bystanders when it left the manufacturer. See *id.* The duties underlying the claims obviously relate fundamentally to both safety and effectiveness, because plaintiffs assert that the alleged failure of the device to continue operating properly endangered Mrs. Lohr. See Conditional Cross-Petition for a Writ of Certiorari at 3.

This Court's recent decisions construing other express preemption provisions confirm that the FDCA language encompasses plaintiffs' claims. Interpreting the express preemption provision of the Employee Retirement Income Security Act of 1974 ("ERISA"), the Court has held that a state law "relates to" an employee benefit plan "if it has a connection with or reference to such plan." *Shaw* v. *Delta Air Lines, Inc.*, 463 U.S. 85, 96-97 (1983). Similarly, the Court has construed the term "relating to" in the express preemption provision of the Airline Deregulation Act of 1978 ("ADA") to mean "having a connection with, or reference to, airline 'rates, routes, or services.' " *Morales* v. *TWA, Inc.*, 374, 384 (1992). Using these decisions as a guide, plaintiffs' common law claims are preempted, because they would establish requirements having a connection with or reference to the safety or effectiveness of the Medtronic device.

Furthermore, in *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. 817, 823 (1995), this Court confirmed that a state requirement can "relate to" a particular subject matter for purposes of preemption without relating to that subject matter

exclusively. Thus, the Court held that claims asserted under the Illinois Consumer Fraud and Deceptive Business Practices Act were preempted by the ADA as "relating to" airline rates, routes, or services, even though the Illinois statute did not relate exclusively to (or even explicitly mention) those matters. Similarly, the common law doctrines invoked by plaintiffs "relate to" safety or effectiveness in this case, and they are preempted by the FDCA.

b. The State Law Requirements Advanced by Plaintiffs' Claims Would "Relate To" Device Design, Which Is a "Matter Included in a Requirement Applicable to the Device" Under the FDCA

It also is indisputable that plaintiffs' claims "relate to" the design of the Model 4011. Those claims have a connection with or reference to device design, because they allege breach of common law duties concerning design.

Claims "relating to" device design are within the FDCA preemption provision. Device design is a "matter included in a requirement applicable to the device" under the FDCA. As discussed at pages 22-28 *supra*, device design is a "matter included in" the 510(k) requirements. Furthermore, the discussion at pages 30-32 *supra* confirms that the 510(k) requirements are "applicable to the device." Plaintiffs' design claims therefore fall squarely within the FDCA preemption provision.

5. Plaintiffs' Design Claims Are Preempted, Because They Would Establish State Requirements "Different from, or in Addition to," Federal Requirements Applicable to the Model 4011

This Court should conclude that plaintiffs' design claims are preempted. Otherwise, they would establish state requirements "different from, or in addition to," the federal requirements imposed by the 510(k) process. The premise of plaintiffs' claims is that the design of the Model 4011 the FDA authorized for marketing violates Florida common law duties. As a result, federal law authorizes marketing of a design that state law, if plaintiffs' claims succeed, would treat as defective. Because the state law requirements are "different from, or in addition to," the federal 510(k) requirements that authorized marketing of the existing design, plaintiffs' claims are preempted. Cf. *Cipollone*, 505 U.S. at 524 (failure to warn claims preempted because they would require "additional, or more clearly stated, warnings" than those required under 1969 Cigarette Act) (Stevens, J.).

Furthermore, plaintiffs' claims are preempted, because they would require Medtronic to change the Model 4011 design authorized by the FDA under federal law. Plaintiffs' claims are premised upon a Florida law duty to use a design for the Model 4011 different from the one the FDA authorized for marketing under federal law through the 510(k) process. Cf. *International Paper Co.* v. *Ouellete*, 479 U.S. 481, 495 (1987) (common law nuisance action would compel company to "adopt different control standards and a different compliance schedule from those approved by the EPA"); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981) ("threat of damages" from common law claims would "require a carrier to do exactly what the [Interstate Commerce] Commission is empowered to ex-

cuse"). Plaintiffs' claims therefore would impose state law design requirements "different from, or in addition to," the 510(k) requirements authorizing marketing of the Medtronic design.

The implications of allowing states to superimpose different or additional requirements on the Model 4011 come into sharp focus if Medtronic were to attempt to conform to the state law requirements established through plaintiffs' claims and immediately change the device design. Under these circumstances, Medtronic would violate the federal regulation restricting design changes in devices previously authorized for marketing under the 510(k) process. As explained above, 21 C.F.R. 807.81(a)(3)(i) bars design changes in a marketed device that could significantly affect safety or effectiveness without an additional 510(k) clearance.[21] In contrast, the state law requirements to be imposed by plaintiffs' claims *by definition* assert that the design should have been significantly safer or more effective. As a result, the design changes demanded by state law would be illegal under federal law absent FDA clearance. If Medtronic changed the

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[21] In administering the FDCA, the FDA consistently has taken the position that product changes require 510(k) clearance even though the manufacturer believes they would *increase* device safety or effectiveness. See, e.g., 42 Fed. Reg. 42,520, 42,522 (Aug. 23, 1977) (preamble to 510(k) regulation). Because the FDA's decisions on 510(k) submissions are committed to the agency's discretion, there is no assurance that the FDA would authorize any changes that Medtronic proposed, even if plaintiffs believed they would enhance device safety. The agency experts may not, for example, agree that the proposed change is safe. In any event, unless and until the FDA *did* authorize such changes, there can be no doubt that Medtronic's duties under state law would be "different from, and in addition to," federal requirements.

design without receiving clearance, its failure to comply with the FDA's 510(k) requirements would render the Model 4011 misbranded under the FDCA,[22] and subject Medtronic to civil and criminal enforcement actions.[23] Under these circumstances, plaintiffs' claims unquestionably would establish state requirements "different from, or in addition to," federal requirements applicable to the device. To make Medtronic choose between compliance with state law requiring design changes and federal law prohibiting them would produce a result wholly inconsistent with the FDCA preemption provision and Supremacy Clause jurisprudence.[24]

D. Preemption Is Consistent with Congress's Overall Design in the FDCA

The words Congress chose in the preemption provision—the best evidence of congressional intent—leave little room to argue that plaintiffs' design claims escape

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[22] See 21 U.S.C. 352(o).

[23] 21 U.S.C. 331(a)-(c), (k), (p), 332-334.

[24] Because the FDCA preempts state requirements whether they are "different from" or "in addition to" federal requirements, there need not be a direct conflict between federal and state law for the express preemption clause to apply. Nonetheless, in this case, there is a direct conflict; the state claims would impose liability for acts authorized under federal law, and the acts required by state law would cause federal violations. Given this conflict, plaintiffs' claims would be impliedly preempted even if this Court were to conclude that plaintiffs' claims were not expressly preempted. See, e.g., *English* v. *General Elec. Co.*, 496 U.S. 72, 79 (1990) (state law is impliedly preempted if it is "impossible for a private party to comply with both state and federal requirements"); *Freightliner Corp.* v. *Myrick*, 115 S. Ct. 1483, 1488 (1995) (existence of an express preemption provision does not foreclose implied preemption arising from actual conflict between federal and state law).

preemption. A brief reflection about the overall design and purposes of the FDCA confirms that the result mandated by the language is sensible and comports with the balance Congress struck among competing interests.

Congress undoubtedly was sensitive to the pain and suffering that can be inflicted by unsafe or ineffective medical devices. But it is just as clear—and pointedly evident in the legislative history of the MDA—that Congress was concerned about the human suffering that will go unremedied if medical devices are removed from, or never introduced to, the market because excessive or variant regulation or substantial regulatory uncertainty inhibits the needed innovation. See S. Rep. No. 33, *supra*, at 2 (Congress sought to encourage research and development of "sophisticated, critically important medical devices").

Common law tort liability is the least predictable form of regulation, and among the most burdensome. Compensation of injured persons is a worthy goal, but the current tort system comes with a price. Decisions are made by juries and judges who lack training in such fields as medical device design, manufacture, and use. Each decision is made after the fact, on an individual basis, and each claim (as the Eleventh Circuit recognized) "would ask the jury to declare what constitutes a reasonable design." Pet. App. 25a. Nor is there any way to ensure that one jury's "finding of fact" on that issue is consistent with any other jury's finding. There is no consistency from state to state even in defining the *general* standards that a device manufacturer is supposed to comply with in order to escape liability; toleration of state variety, a virtue of federalism in some contexts, comes with the price of allowing different states to impose different standards of liability.

In 1976, Congress chose what it believed to be a better way to regulate medical devices. It concluded that the FDA, working with panels of experts, and with the ability to consider *all* the costs, benefits, and risks of a particular design, could make more accurate decisions about "what constitutes a reasonable design" (Pet. App. 25a) than could a lay jury confronted only with the facts of one particular case and aided only by the testimony of the parties' chosen expert witnesses. Furthermore, by concentrating regulation at the federal level, Congress believed that it could minimize uncertainty, promote uniformity, and spur innovation that would not be "stifled by unnecessary restrictions." H.R. Rep. No. 853, *supra*, at 12; cf. *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981) ("A system under which each State could, through its courts, impose on railroad carriers its own version of reasonable service requirements could hardly be more at odds with the uniformity contemplated by Congress in enacting the Interstate Commerce Act.").

There admittedly are some costs associated with preempting state common law. Nonetheless, Congress was willing to accept those costs in order to have a regulatory system that would best serve the *many* persons who benefit from a medical device industry that is carefully regulated at the federal level by experts and not hamstrung by a patchwork of state requirements that are superimposed on the federal requirements. Because the scheme Congress chose has provided companies like Medtronic with a regulatory environment conducive to innovation, thousands of persons—including Mrs. Lohr herself—continue to benefit from life-enhancing device technology.

Congress was willing to see *some* supplementation of federal requirements, but not—as plaintiffs and the Eleventh Circuit contend—by tolerating common law design claims

such as Mrs. Lohr's. Instead, the process for supplementing federal requirements with state requirements is the exemption process under 21 U.S.C. 360k(b). It was the intent of Congress that unless the FDA has granted an exemption from preemption, state requirements fall within the "general prohibition on non-Federal regulation." H.R. Rep. No. 853, *supra*, at 45. This Court should honor that congressional intent and hold that the common law design claims at issue in this case are preempted.

CONCLUSION

The Court should reverse in part the judgment of the Eleventh Circuit and hold that the Federal Food, Drug, and Cosmetic Act preempts plaintiffs' negligence and strict liability claims regarding the design of the Medtronic Model 4011 cardiac pacemaker lead.

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